



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Care Safety and Quality
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MEMORANDUM

TO: Interested Parties
FROM: Madeleine Biondolillo, M.D., Director, Bureau of Health Care Safety and Quality, Iyah Romm, Director of Policy, Health Planning, and Strategic Development, and Bernard Plovnick, Director, Determination of Need Program
DATE: November 9, 2012
SUBJECT: Chapter 224 of the Acts of 2012 as it relates to Determination of Need (DoN)

Chapter 224 of the Acts of 2012 is effective as of November 5, 2012. The purpose of this memorandum is to provide guidance to interested persons until the Department promulgates amendments to 105 CMR 100.00, the regulation governing the Determination of Need (DoN) program, in regard to the following:

- Creation of new Center for Health Information and Analysis: Until such time as the regulation is updated, applicants and other parties should consider that any reference of the regulation to the Division of Health Care Finance and Policy (DHCFP) should be interpreted as applying to its successor entity, the Center for Health Information and Analysis (CHIA).
- Creation of new Health Policy Commission: Applicants must submit a copy of any application submitted after November 5, 2012 to the Health Policy Commission (HPC). Contact information will be added to the Department's website when it is available; in the interim, the Department of Public Health will forward copies of the application to the Health Policy Commission.
- Filing for a Research Exemption pursuant to M.G.L. c. 111, § 25C: Any party that files for a research exemption must submit a copy of the filing to CHIA and the new HPC. Such parties should also be aware of new penalties under section 25C for violations of the DoN requirements regarding research projects.
- Ambulatory Surgery: Section 67 of chapter 224 amends the definition of "ambulatory surgery" to make it clear that wherever DoN applies to ambulatory surgery, it does so whether the facility is an ambulatory surgery center (an outpatient facility licensed as a clinic) or a hospital. Thus, an addition or expansion of ambulatory surgery would be a

substantial change of service even for a hospital, notwithstanding the current language in the regulation.

- Innovative Service. Section 68 of chapter 224 amends the definition of “innovative service.” Although the new definition is less prescriptive and allows DPH to determine what constitutes an “innovative service,” applicants may continue to rely on the Department’s current list of innovative services until further notice.
- New Technology. Section 69 of chapter 224 amends the definition of “new technology.” Although the new definition is less prescriptive and allows DPH to determine what constitutes a “new technology,” applicants may continue to rely on the Department’s current list of new technology until further notice.
- Medical, diagnostic or therapeutic equipment (other than in a health care facility)

Paragraph (d) in the revised section 25C requires notice to DPH of any equipment other than an innovative service or new technology in excess of \$250K with annual inflation adjustments (had been \$150K with no inflation adjustment). Other changes are technical revisions with the exception of a provision that previously prohibited self-referral by non-physicians for MRIs; this prohibition now applies to all “new technology”.

Paragraph (e) in the revised section 25C requires entities operating the equipment to annually submit data on utilization and volume.

- Review of applications: Paragraph (g) in the revised section 25C adds to the factors DPH must consider in review of DoN applications. DPH must now consider *inter alia* any comments from the new CHIA, comments from the new HPC, and from any other agency (the Attorney General, for example, may intervene).
- Fees: Paragraph (h) in the revised section 25C permits the Department to increase the DoN filing fee from .1 percent to .2 percent. Until such time as the Department establishes a new fee by regulation, the current fee remains in effect.

Please direct questions concerning these provisions to Bernard Plovnick, DoN Director, at bernard.plovnick@state.ma.us.